

PATENT
Docket No. 220022001600

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Assistant Commissioner for Patents, Washington, D.C. 20231, on March 31, 2003.


Rhca Amid

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#18

In the application of:

Tom F. LUE, et al.

Serial No.: 09/909,544

Filing Date: July 19, 2001

For: METHODS AND COMPOSITIONS FOR
PREVENTING AND TREATING MALE
ERECTILE DYSFUNCTION AND
FEMALE SEXUAL AROUSAL
DISORDER

Examiner: Celine X. Qian

Group Art Unit: 1636

DECLARATION OF TOM F. LUE PURSUANT TO 37 C.F.R § 1.132

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

I, Tom F. Lue, in my individual capacity, hereby declares as follows:

1. I am one of the co-inventors of the above-referenced patent application, and am familiar with the contents thereof.

Bakircioglu

2. I have reviewed the publication entitled "The effect of adeno-associated virus-mediated brain-derived neurotrophic factor in an animal model for neurogenic impotence," published in *Journal of Urology*, Vol. 163, No. 4 Suppl., pp. 198 (April, 2000) (Bakircioglu), and cited by the Examiner, for which I am a co-author. The publication was cited by the Examiner as prior art against the application under 35 U.S.C. § 102(a).

3. The publication cited describes work that is encompassed by this patent application and its parent applications. The co-authors, Bakircioglu, M.E., Wefer, J., Sievert, KD and Fan, P., named in the publication were not involved in the conception of the subject matter of the presently claimed invention. Moreover, these co-authors worked under my and other co-inventors' direction performing work that led to the invention, but did not make an inventive contribution to the subject matter of the presently claimed invention.

Treatment of erectile dysfunction with vascular changes by BDNF

4. My co-inventors and I have performed, or have directed others to perform, experiments that show that a high fat diet caused erectile dysfunction with accompanying neurological and vascular changes. The changes include less nerve content, fewer endothelial cells and lighter smooth muscle content, hypermyelination and severe atrophy of axons, a remarkable decrease in the number and size of nonmyelinated axons, disarray of the smooth muscle cells with scant myofilaments and foamy cytoplasm and denuded endothelial lining of the sinusoids covered by numerous platelets (*See Exhibit 1, Gholami et al., "The Effect of Vascular Endothelial Growth Factor and Adeno-Associated Virus Mediated Brian Derived Neurotrophic Factor on Neurogenic and Vasculogenic Erectile Dysfunction Induced by Hyperlipidemia," to be published in J. Urology (2003)*). Our experiments also show that treatment with BDNF, *e.g.*, AAV-BDNF, alleviates, at least partially, these changes.

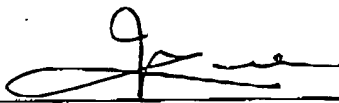
Prevention of erectile dysfunction by BDNF treatment

5. My co-inventors and I have performed, or have directed others to perform, experiments that show that, after nerve crush, BDNF/VEGF treatment can prevent and facilitate regeneration of nNOS containing neurons in the major pelvic ganglia, dorsal never and intracavernous tissue (See Exhibit 2. Bochinski et al., "The Effect of Vascular Endothelial Growth Factor and Brian Derived Neurotrophic Factor on Cavernous Nerve Regeneration in a Nerve-Crush Rat Model," manuscript submitted to British Journal of Urology). This result indicates that BDNF can have preventive, as well as therapeutic, effect to the erectile dysfunction.

6. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

March 17, 2003

Date



Tom F. Lue

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GROUP 1600

To: Celine X. Qian, Examiner
Group Art Unit 1636
U.S. Patent and Trademark Office

Facsimile: (703) 305-3014
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OFFICIAL**From: Peng Chen****Date: June 13, 2003**

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Comments:

Re: U.S. Pat. Appln No. 09/909,544, Filed: July 19, 2001
Our Ref: 22002-20016.00

Dear Examiner Qian:

Per our conversation this date, attached are copies of the return receipt postcard and executed Declaration as mailed on March 31, 2003.

Regards,**Peng Chen**

Inventor: Tom F. Lue, et al.

Atty Docket No.: 220022001600

Application No.: 09/909,544

Filing Date: July 19, 2001

Title: METHODS AND COMPOSITIONS FOR PREVENTING AND TREATING MALE
ERECTILE DYSFUNCTION AND FEMALE SEXUAL AROUSAL DISORDER

Documents Filed:

Transmittal (1 page)

Executed Declaration

Via: First Class Mail

Sender's Initials: PChen/rxa5

Date: March 31, 2003

Atty Docket No.: 220022001600

Inventor: Tom F. Lue, et al.

Application No.: 09/909,544

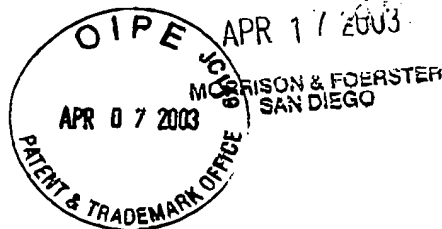
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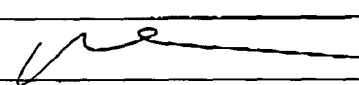
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TRANSMITTAL FORM <i>(to be used for all correspondence after initial filing)</i>	Application Number	09/909,544	
	Filing Date	July 19, 2001	
	First Named Inventor	Tom F. Lue	
	Group Art Unit	1636	
	Examiner Name	Celine X. Qian	
Total Number of Pages in This Submission	4	Attorney Docket Number	220022001600

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<div style="display: flex; justify-content: space-between;"> <div>Remarks</div> <div style="text-align: center;">  25225 PATENT, TRADEMARK OFFICE </div> </div>		

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Firm or Individual Name	MORRISON & FOERSTER LLP Peng Chen - 43,543
Signature	
Date	March 31, 2003

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Dated: 3-31-03Signature:  (Rhea Amid)